#### **MINUTES**

# KENTUCKY BOARD OF PHARMACY

Frankfort, Kentucky June 9, 2004

<u>CALL TO ORDER:</u> A regular meeting of the Kentucky Board of Pharmacy was held at the Board office, 23 Millcreek Park, in Frankfort, Kentucky. President Armstrong called the meeting to order at 9:10 a.m.

Members present: Tim Armstrong, Becky Cooper, Mark S. Edwards, Georgina Kindall Jones, Greg Naseman and Patricia Thornbury. Staff present: Jeffrey L. Osman, Interim Executive Director; Katie Busroe and Philip C. Losch, Pharmacy and Drug Inspectors; Cheryl Lalonde-Mooney, Assistant Attorney General and Board Counsel; and Shannon Settles, Executive Secretary. Guests: Mike Mayes, KPhA; Jan Gould, Kentucky Retail Federation; Brian Fingerson, Pharmacist Recovery Network; Nancy Horn, APSC; Ralph Bouvette, APSC; J.D. Hammond, APSC; Mark Brengleman, Assistant Attorney General; Paula York, Drug Control; Mike Wyant, Hancy Jones III; Joel Thornbury; Allison Cubit and Chris Clifton, University of Kentucky students; Dr. Trish Freeman; Dr. Holly Devine; Dr. Christy Taylor; and Margaret Pisacano. Juanita Toole, Court Reporter, recorded the meeting.

## **APPEARANCE:**

**John McKnight.** Dr. McKnight appeared before the Board to request approval to sit for the Kentucky Practical Examination. Dr. McKnight's intern card expired June 2003, therefore, he did not have a valid intern card during his fourth year rotations. After a brief discussion, Ms. Thornbury moved to allow Dr. McKnight to sit for the Kentucky Practical Examination and pay an administrative fine of \$250.00. Ms. Jones seconded and the motion passed unanimously.

Immunization Task Force/ Dr. Trish Freeman, Dr. Holly Devine, Dr. Christy Taylor. Dr. Freeman provided the Board with the recommendation of the Immunization Task Force. The overall consensus of the Task Force was that no regulations are needed at this time. Mr. Naseman moved to accept the recommendation of the Immunization Task Force. Ms. Jones seconded and the motion passed. Ms. Jones suggested that the recommendation of the Immunization Task Force be placed in the next newsletter. Ms. Cooper and Mr. Edwards opposed.

**Joel Thornbury, Allison Cubit, Chris Clifton.** Mr. Thornbury, Ms. Cubit, and Mr. Clifton appeared before the Board to express the University of Kentucky students' concerns on the Kentucky Practical Examination possibly being given in July instead of June next year.

Mr. Thornbury presented former President Kindall Jones with a plaque from KPhA for her previous year's service as Board President.

**MINUTES:** On motion by Mr. Naseman, seconded by Mr. Edwards and passed unanimously, the Minutes of May 18, 2004 were adopted.

**INTERAGENCY:** Paula York. Paula York informed the Board that as of June 15, 2004 Drug

Control would no longer be under Public Health. Drug Control will now be under Office of the Inspector General.

**BOARD REPORTS: President.** President Armstrong stated that the search for Executive Director is on-going.

President Armstrong stated the importance of a task force and would like to see more being developed. He would like to reenact the Pharmacy Advisor Committee.

President Armstrong thanked Board staff.

**Interim Executive Director.** Dr. Osman informed the Board that he has been contacted by the Governor's Office and they intend to take \$21,700 from the Board account and transfer it to the General Fund.

Dr. Osman informed the Board that the Board is short two proctors for the Kentucky Practical Examination. Ms. Thornbury moved to allow Mr. Joe Carr and Mr. David Jaquith, both former Board members, to help with the Examination. Ms. Cooper seconded and the motion passed unanimously.

Dr. Osman informed the Board that the Board has received approval from the Finance & Administration Cabinet for the purchase of new computers and software for the Board office.

CURRENT/PENDING CASES: Mr. Edwards moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Cooper seconded and the motion passed unanimously. Case No. 98-0181; Case No. 03-0011A; Case No. 03-0011B; Case No. 03-0057; Case No. 03-0061A, Case No. 03-0098A; Case No. 03-0098B; Case No. 03-0141A; Case No. 03-0145; Case No. 03-0158A; Case No. 03-0158B; Case No. 04-0010A; Case No. 04-0010B; Case No. 04-0023; Case No. 04-0038; Case No. 04-0039A; Case No. 04-0039B.

### **CASE REVIEW COMMITTEE**

Mr. Edwards moved for acceptance of the Committee recommendation for the following case reports,

Case No. 02-0150. The Board office was forwarded a complaint from the Kentucky Board of Respiratory Care regarding a special limited medical gas permit holder. The complaint has several allegations that do not pertain to the Board of Pharmacy. The two allegations that do pertain to the Board of Pharmacy are (1) transfilling oxygen cylinders and (2) dispensing respiratory medicines to patients without a prescription. Alleged violations of law: CGA P-2.5 *Transfilling of High Pressure Gaseous Oxygen to Be Used for Respiration*, KRS 315.121(2)(f) and KRS 315.035(1). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously. Case No. 02-0165B Revisit. Pharmacist-in-charge allegedly engaged in unprofessional conduct by not having quality assurance programs in place that would resolve identified problems that exist. On

3 separate occasions in an eight month time frame, a patient was not given the entire quantity of her prescription. Various pharmacists were responsible for the 3 alleged medication errors. Alleged violations of law: 201 KAR 2:205 and KRS 315.121. CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0075 Revisit. Indiana Board of Pharmacy entered an Order indefinitely suspending the pharmacist's license to practice pharmacy in the state of Indiana. On December 3, 2003 Pharmacist entered into an Agreed Order of Suspension with the Kentucky Board of Pharmacy until such time as the Indiana State Board of Pharmacy agrees to reinstate his license, whereupon, the Pharmacist may petition to reinstate his Kentucky license. The pharmacist's Kentucky license that was surrendered is not in the file. The Indiana Board of Pharmacy had a hearing on October 21, 2003, at which time the pharmacist was ordered to successfully pass the MPJE. After doing so an order of indefinite probation will be entered. The Kentucky Board of Pharmacy renewed his license on March 4, 2004. Alleged violations of law: KRS 315.121(1)(c) and (I). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0134 Revisit. Pharmacy permit holder allegedly closed pharmacy without proper notification to the Board office or public. The Board office received an e-mail complaint from a consumer that when she went to pick up her prescriptions the pharmacy was closed. According to posted hours, the pharmacy should have been open. Alleged violation of law: KRS 315.121(2)(d). The Board office drafted an Agreed Order with a fine of \$5000. The pharmacy permit holder would like the amount of the fine to be reconsidered. CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0156A Revisit. Pharmacy corporation allegedly failed to provide proper security of controlled substances at four pharmacies. A DEA 106 Theft/Loss report showed substantial losses of controlled substances. A pharmacy technician was stopped for a traffic violation and the vehicle searched. Several stock bottles of controlled substances were found. An investigation revealed that the technician had been diverting controlled substances from four pharmacies for several years. Furthermore, the pharmacy permit holder failed to notify the Board office of pharmacist-in-charge changes. Alleged violations of law: 201 KAR 2:100, KRS 315.020(1), and KRS 315.121(2)(d) and (e). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0156B Revisit. Pharmacist-in-charge allegedly failed to provide proper security of controlled substances. A DEA 106 Theft/Loss report showed substantial losses of controlled substances. A pharmacy technician was stopped for a traffic violation and the vehicle searched. Several stock bottles of controlled substances were found. An investigation revealed that the technician had been diverting controlled substances from four pharmacies for several years. This pharmacy lost more than 34,000 dosage units over an 18 month time frame. The pharmacist-in-charge identified problem areas with this technician such as change in attitude, long bathroom breaks, not following store policy, shortages of controlled substances, and more. The pharmacist-in-

charge did not follow through on the problem technician, but allowed him to transfer to another store. Alleged violations of law: 201 KAR 2:100, 201 KAR 2:205 Section 2 (3)(a)(b), and KRS 315.121(1)(j) and (2)(d) and (e). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0156C Revisit. Pharmacist-in-charge allegedly failed to provide proper security of controlled substances. A DEA 106 Theft/Loss report showed substantial losses of controlled substances. A pharmacy technician was stopped for a traffic violation and the vehicle searched. Several stock bottles of controlled substances were found. An investigation revealed that the technician had been diverting controlled substances from four pharmacies for several years. This pharmacy lost more than 78,000 dose units over a 6 month time frame. The pharmacist-in-charge was on family leave from December 12, 2002 through March 15, 2003, however, the Board office was not notified of pharmacist-in-charge changes for this time period. Pharmacist-in-charge became aware of diversion soon after returning from family leave and alerted risk management. Alleged violations of law: 201 KAR 2:100, 201 KAR 2:205 Section 2 (2)(b), (3)(a),(b), and (d)(1) and KRS 315.121(2)(d) and (e). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0156D Revisit. Pharmacist-in-charge allegedly failed to provide proper security of controlled substances. A DEA 106 Theft/Loss report showed minimal losses of controlled substances. A pharmacy technician was stopped for a traffic violation and the vehicle searched. Several stock bottles of controlled substances were found. An investigation revealed that the technician had been diverting controlled substances from four pharmacies for several years. This was the first pharmacy of employment for the technician. He was at this pharmacy for approximately six months and the audit revealed minimal discrepancies. Alleged violations of law: 201 KAR 2:100, 201 KAR 2:205 Section 2 (3)(b), and KRS 315.121(2)(d) and (e). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 03-0156E Revisit. Pharmacist-in-charge allegedly failed to provide proper security of controlled substances. A DEA 106 Theft/Loss report showed minimal discrepancies of controlled substances. A pharmacy technician was stopped for a traffic violation and the vehicle searched. Several stock bottles of controlled substances were found. An investigation revealed that the technician had been diverting controlled substances from four pharmacies for several years. The technician was employed at this pharmacy for approximately two years. The audit revealed minimal discrepancies with the exception of an overage of 16,000 hydrocodone/APAP 5/500. Alleged violations of law: 201 KAR 2:100, 201 KAR 2:205 Section 2 (3)(b), and KRS 315.121(2)(d) and (e). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-033A. Pharmacy permit holder allegedly sold a misbranded product as the result of multiple medication errors on a single prescription. A prescription for patient A was presented to the pharmacist for Strattera 40mg. The prescription was filled for patient B with Strattera 25mg. Patient B received the Strattera and was administered the drug according to the directions on the label. Patient B was hospitalized on two separate occasions as the result of consuming the Strattera

that was prescribed for patient A. Alleged violation of law: KRS 217.065. CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-033B. Pharmacist allegedly engaged in unprofessional conduct by committing multiple medication errors on a single prescription. A prescription for patient A was presented to the pharmacist for Strattera 40mg. The prescription was filled for patient B with Strattera 25mg. Patient B received the Strattera and was administered the drug according to the directions on the label. Patient B was hospitalized on two separate occasions as the result of consuming the Strattera that was prescribed for patient A. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-035. Pharmacy permit holder allegedly engaged in unprofessional conduct by refusing to dispense a prescription until payment from insurance was confirmed. A prescription for a child for an antibiotic, Zithromax, was presented to the pharmacist. The insurance was down and the pharmacist would not dispense the prescription until payment could be confirmed. The parent made at least two trips to the pharmacy to pick up the prescription. On the last trip the parent asked for the prescription hard copy to be returned. The pharmacist refused. At this time, the parent was given the filled prescription. It was approximately 4.5 hours from the time the prescription was dropped off at the pharmacy to the time of adjudication by the insurance. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-040. Pharmacist allegedly engaged in unprofessional conduct by practicing as a pharmacist using an assumed name. Pharmacist allegedly failed to maintain accurate pharmacy records, committed several medication errors, dispensed a legend drug without a valid authorization from a licensed practitioner, and failed to perform prospective drug utilization review. The Board office received a complaint that a pharmacist was practicing pharmacy using a name that was not the name issued to the Kentucky pharmacist's license number that was being used. In addition, several medication errors were made including but not limited to wrong directions, wrong patient, wrong prescriber, and wrong quantity. Pharmacist allegedly failed to perform a prospective drug utilization review and dispensed a medication to a long term care facility patient that had documented allergy to the medication. Pharmacist allegedly dispensed legend medication without a valid authorization from a licensed practitioner. Alleged violations of law: KRS 315.030(2), KRS 315.121(1)(a)(g), KRS 315.121(2)(d)(g)(h), 201 KAR 2:170 Section 1 (3)(8)(11), KRS 218A.180(6), and KRS 217.065(1). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-041A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. A prescription was presented to be refilled for metoprolol 50 mg, however, allopurinol 300 mg was dispensed instead. The vial was labeled as metoprolol 50 mg. The patient experienced various symptoms from taking the allopurinol and went to her physician. Alleged violation of law: KRS 217.065. CRC recommendation for Complaint with attempt to resolve

through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-041B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented to be refilled for metoprolol 50 mg, however, allopurinol 300 mg was dispensed. The vial was labeled as metoprolol 50 mg. The patient experienced various symptoms from taking the allopurinol and went to her physician. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-042A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. A prescription was presented for Betimol 0.5% eye drops. The prescription was filled with Betimol 0.25% eye drops. The error was corrected on the first refill. Alleged violation of law: KRS 217.065. CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-042B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented for Betimol 0.5% eye drops. The prescription was filled with Betimol 0.25% eye drops. The error was corrected on the first refill. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-047A. Pharmacy permit holder allegedly sold a misbranded product. A stock bottle of diclofenac 75 mg was in the patient's bag along with her labeled prescription vial. Alleged violations of law: KRS 217.065 (6)(a) and (11)(b). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-047B. Pharmacist allegedly engaged in unprofessional conduct by dispensing a stock bottle of a legend drug without proper labeling. A stock bottle of diclofenac 75 mg was in the patient's bag along with her labeled prescription vial. Alleged violations of law: KRS 217.065 (6)(a) and (11)(b) and KRS 315.121(2)(d). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-060A. Pharmacy permit holder allegedly engaged in unprofessional conduct by having a pharmacist counsel a pediatric patient's mother inappropriately. The mother of a one month old child presented at least two prescriptions to the pharmacist, Xopenex 0.63%, use 1 ampule in nebulizer twice daily and Pulmocort 0.25, use 1 ampule in nebulizer twice daily. The written directions did not match the verbal directions given to the mother. The pharmacist suggested the mother check with the physician in the morning since the office had already closed. The pharmacist telephoned the mother later that evening to follow up on the condition of the infant. The mother took her infant to another pediatrician within 4 days for a second opinion. This pediatrician discontinued the Xopenex. The complaint came from the original prescribing physician. Alleged violations of law: KRS 315.121(2)(d) and (e). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-060B. Pharmacist allegedly engaged in unprofessional conduct by counseling a

pediatric patient's mother inappropriately. The mother of a one month old child presented at least two prescriptions to the pharmacist, Xopenex 0.63%, use 1 ampule in nebulizer twice daily and Pulmocort 0.25, use 1 ampule in nebulizer twice daily. The written directions did not match the verbal directions given to the mother. The pharmacist suggested the mother check with the physician in the morning since the office had already closed. The pharmacist telephoned the mother later that evening to follow up on the condition of the infant. The mother took her infant to another pediatrician within 4 days for a second opinion. This pediatrician discontinued the Xopenex. The complaint came from the original prescribing physician. Alleged violations of law: KRS 315.121(2)(d) and (e) and 201 KAR 2:210 Section 2(4)(b). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-061. Pharmacist allegedly failed to complete 1.5 units of continuing education in 2003. Pharmacist self reported on 2004 Kentucky pharmacist's renewal application that he had only obtained 0.675 units of continuing education in 2003. Alleged violations of law: KRS 315.065(2) and 201 KAR 2:015. CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-062. Pharmacist allegedly failed to renew pharmacist's license in a timely manner and continued to practice pharmacy. Pharmacist renewed pharmacist's license on March 2, 2004. Alleged violation of law: KRS 315.110(1). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

Case No. 04-063. Pharmacist allegedly failed to renew pharmacist's license in a timely manner and continued to practice pharmacy. Pharmacist renewed pharmacist's license on March 22, 2004. Alleged violation of law: KRS 315.110(1). CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

**Case No. 04-064.** Pharmacy permit holder allegedly failed to have a pharmacist-in-charge for approximately 40 days. Alleged violations of law: KRS 315.020(1) and 201 KAR 2:205. CRC recommendation for Complaint with attempt to resolve through AO. Mr. Naseman seconded and the motion passed unanimously.

### RECIPROCITY/RELICENSURE/INTERNSHIP:

**Alan Waldman.** The Board reviewed correspondence from Mr. Waldman requesting reinstatement of his Kentucky license. After a brief discussion, Ms. Thornbury moved to approve Mr. Waldman reinstatement of his license after he successfully takes the MPJE examination. Ms. Cooper seconded and the motion passed unanimously.

**CORRESPONDENCE:** Brian Fingerson. The Board reviewed correspondence from Mr. Fingerson requesting an increase for his compensation for administering the Impaired Pharmacist Program. Mr. Edwards moved to approve the increase. Ms. Jones seconded and the motion passed unanimously.

Beringer Drug Center/ Jennifer Grove. The Board reviewed correspondence from Dr. Grove

regarding prescriber's representatives phoning in an order that consists of the words "OK to refill all regular meds." After a brief discussion, the Board authorized Dr. Osman to respond that this would be considered an invalid order. Ms. Thornbury requests an article in the newsletter and forward a letter to the Kentucky Board of Medical Licensure.

**Michael Farrell.** The Board reviewed correspondence from Mr. Farrell regarding amendment of his Agreed Order to allow him to be the pharmacist-in-charge at Thriftway in Newport, Ky. After a brief discussion, Mr. Edwards moved to approve the request. Mr. Naseman seconded and the motion passed unanimously.

Wish's Drugs/Frank Wishnia. The Board reviewed correspondence from Mr. Wishnia regarding consumers purchasing their prescription medications via mail through Canada. After a brief discussion the Board continued this matter until the August meeting.

**Melanie Mabins.** The Board reviewed correspondence from Ms. Mabins requesting an exemption from taking a portion of the Kentucky Practical Examination on Sunday. After a brief discussion, Ms. Jones moved to deny the request. Ms. Thornbury seconded and the motion passed unanimously.

**Larry Spears.** The Board reviewed correspondence from Mr. Spears requesting a reduction in the hours of operations for American Generic Mail Order Pharmacy. After a brief discussion, Mr. Edwards moved to approve the request to reduce the operating hours to 5 hours per week. Ms. Thornbury seconded and the motion passed unanimously.

**Avenue Pharmacy/John Vaal.** The Board reviewed correspondence from Mr. Vaal regarding the legality of sending a pharmacist with a laptop computer to senior citizen centers in the area and the legality of setting up a satellite pharmacy inside a grocery store. After a brief discussion, Ms. Jones moved to authorize Dr. Osman to respond to Mr. Vaal's request that use of the laptop was permissable, but the satellite pharmacy would be considered a drop off station unless licensed by the Board and staffed by a pharmacist. Mr. Edwards seconded and the motion passed unanimously.

**St Matthews Medical Associates/Patricia Barber.** The Board reviewed correspondence from Ms. Barber stating that St Matthews Medical Associates uses a pharmacy system called Prescribe. The company has the ability to send the prescriptions, new or refills, through ProxyMed who in turn faxes the information to the pharmacies. Some pharmacist say they cannot accept the refills and/or new prescriptions because they do not have a physician's signature. After a brief discussion, the Board authorized Dr. Osman to respond to Ms. Barber's concerns on new prescriptions that the image of electronic signature has to appear on the prescription.

**CONTINUING EDUCATION:** 

**Program Approval.** Mr. Edwards moved to accept the continuing education programs 04-19 through 04-23. Ms. Jones seconded and the motion passed unanimously.

# **NEW BUSINESS:**

Ms. Cooper informed the Board that she had looked into updating the Board's website, however, due

to the ancient system the Board would need to hire a webmaster to update the site. Ms. Lalonde-Mooney informed the Board that there is a webmaster through state government that could update the website, or this could be done through contract with an outside vendor. Ms. Cooper moved to have Dr. Osman search for an inexpensive webmaster vendor. Ms. Thornbury seconded and the motion passed unanimously.

Ms. Thornbury expressed her concerns about the discussion of Continued Professional Development that is going to be a topic at the District III meeting in Biloxi MS in August.

**ADJOURNMENT:** On motion by Mr. Edwards, seconded by Ms. Thornbury and passed unanimously, President Armstrong adjourned the meeting at 1:18 p.m. The next Board meeting is scheduled to begin at 9:00 a.m. on August 11, 2004.

Jeffrey L. Osman, Interim Executive Director